PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference JWJ01047WO	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/GB2004/003773	International filing date *(day/month/year)* 02.09.2004	Priority date *(day/month/year)* 03.09.2003
International Patent Classification (IPC) or national classification and IPC C12Q1/68		
Applicant RANDOX LABORATORIES LTD		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 8 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *sent to the applicant and to the International Bureau)* a total of sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
21.03.2005	19.08.2005
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Gabriels, J Telephone No. +31 70 340-4282

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/GB2004/003773

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-14 as originally filed

Sequence listings part of the description, Pages

1-2 as originally filed

Claims, Numbers

1-13 as originally filed

Drawings, Sheets

1/2-2/2 as originally filed

☒ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/GB2004/003773

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. -

because:

☒ the said international application, or the said claims Nos. 1-5 (with respect to IA) relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. -

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/GB2004/003773

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	2,7,9,10,11
	No:	Claims	1,3-6,8,12,13
Inventive step (IS)	Yes:	Claims	2,7,9,10,11
	No:	Claims	1,3-6,8,12,13
Industrial applicability (IA)	Yes:	Claims	6-13
	No:	Claims	1-5

2. Citations and explanations (Rule 70.7):

see separate sheet

Supplemental Box relating to Sequence Listing

Continuation of Box I, item 2:

1. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this report has been established on the basis of:

   a. type of material:

   ☒ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☒ in written format

   ☒ in computer readable form

   c. time of filing/furnishing:

   ☒ contained in the international application as filed

   ☒ filed together with the international application in computer readable form

   ☐ furnished subsequently to this Authority for the purposes of search and/or examination

   ☐ received by this Authority as an amendment on

2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional observations, if necessary:

III. Non-establishment of opinion (Continuation)

Claims 1-5 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

V. Reasoned statement (Continuation)

2.1 CITATIONS

Reference is made to the following documents:

D1: WO 01/92581 A (HARLOCKER SUSAN L ; ALGATE PAUL A (US); CORIXA CORP (US); JONES ROBERT) 6 December 2001 (2001-12-06)

D2: WO 03/061386 A (ZAPATA-BENAVIDES PABLO ; LOPEZ BERESTEIN GABRIEL (US); TARI ANA MARIA) 31 July 2003 (2003-07-31)

D3: WO 02/092854 A (NOVARTIS AG ; DRESSMAN MARLENE MICHELLE (US); LAVEDAN CHRISTIAN NICOLA) 21 November 2002 (2002-11-21)

2.2 NOVELTY (Art. 33(2) PCT)

2.2.1 D1 discloses compositions and methods for the therapy and diagnosis of ovarian cancer. Illustrative compositions comprise one or more ovarian tumor polypeptides, immunogenic portions thereof, polynucleotides that encode such polypeptides. The disclosed compositions are useful, for example, in the diagnosis, prevention and/or treatment of ovarian cancer (cf. pages 385 line 27 to page 392 line 27 and claims 1, 4-7). SEQ ID NO: 10564 of D1 is comprised within SEQ ID NO: 1. D1 does not disclose the gene with SEQ ID NO:2 which is comprised in SEQ ID NO:1. It is however clear that SEQ ID NO:1 contains other open reading frames then SEQ ID NO:2. Claim 1 does not specify that the gene concerned is SEQ ID NO:2. Furthermore, claim 1 only mentions cancer in general. The teaching of D1 therefore falls within the scope of claims 1, 3-6, 8, 12, and 13. In view of D1, claims

1, 3-6, 8, 12, and 13 are not novel.

2.2.2 D2 discloses methods for inhibiting the growth of breast cancer cells and methods for treating breast cancers expressing the WT1 gene product using a WT1 antisense oligonucleotide. D2 does not disclose the gene used in the present application.

2.2.3 D3 discloses methods for treating and monitoring the progression of breast carcinoma based on genes which are differentially expressed in breast tumors. Also disclosed are methods for identifying agents useful in the treatment of breast carcinoma, methods for monitoring the efficacy of a treatment for breast carcinoma, methods for inhibiting the proliferation of a breast carcinoma, and breast, specific vectors including the promoters of the disclosed genes. D3 does not disclose the gene used in the present application.

2.2.4 Claims 2,7,9,10,11 are novel and thus satisfy the criterion set forth in Article 33(2) PCT.

2.2.5 The present application does not satisfy the criterion set forth in Article 33(2) PCT because the subject-matter of claims 1, 3-6, 8, 12, and 13 is not new in respect of prior art as defined in the regulations (Rule 64(1)-(3) PCT).

2.3 INVENTIVE STEP (Art. 33(3) PCT)

2.3.1 Document D3 is considered to represent the most relevant state of the art (cf 2.2.4). The subject-matter of claims 2,7,9,10,11 differs in that the gene with SEQ ID NO:2 (comprised within SEQ ID NO:1) is used.

2.3.2 The problem to be solved by the subject matter of claims 2,7,9,10,11 may therefore be regarded as improving the diagnosis and treatment of breast cancer. The solution would be the use of the gene with SEQ ID NO:2.

2.3.2.1 The gene described in the present application was partly known from D1 and could be involved in ovarian cancer. There is however no indication in the prior art which

would implicate this gene in breast cancer. It would therefore not be obvious for the skilled person to use this gene for the diagnosis and treatment of breast cancer.

2.3.2.2 Claims 2,7,9,10,11 are inventive and thus satisfy the criterion set forth in Article 33(3) PCT.

2.3.3 The present application does not satisfy the criterion set forth in Article 33(3) PCT and the subject-matter of claims 1, 3-6, 8, 12, and 13 does not involve an inventive step (Rule 65(1)(2) PCT).